UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN
MILWAUKEE DIVISION

UNITED STATES OF AMERICA ex rel.
ELIZABETH KELTNER

Court File No. 11-cv-0892

STATE OF WISCONSIN ex rel.
ELIZABETH KELTNER

Plaintiffs,

v.

LAKESHORE MEDICAL CLINIC, LTD.,

Defendant.

DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS FIRST AMENDED COMPLAINT

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INTRODUCTION

Plaintiff Elizabeth Keltner ("Relator"), purporting to act as a qui tam relator, has brought claims against defendant Lakeshore Medical Clinic, Ltd. ("Lakeshore") under the federal False Claims Act, 31 U.S.C. §§ 3729-3731 ("FCA") and the Wisconsin False Claims Act, Wis. Stat. § 20.931. In her First Amended Complaint ("Amended Complaint"), Relator alleges that Lakeshore submitted false claims for payment of health care services to the Centers for Medicare and Medicaid Services ("CMS") and the Wisconsin Department of Health Services ("WDHS"). Relator alleges at least 12 separate fraudulent schemes by Lakeshore, including "upcoding," billing for medically unnecessary services, "unbundling," and charging for services never performed. In addition, Relator claims that Lakeshore retaliated against her by terminating her employment when she brought these issues to management's attention.

Relator's claims are fatally flawed for several reasons. First, Relator bases her claims on regulatory "violations" that are largely imaginary. At best, Relator's allegations raise legitimate disputes over the interpretation of CMS regulatory guidance. Often, however, she simply misinterprets or misapplies the relevant regulations and guidance. These allegations must be dismissed under Rule 12(b)(6) for failure to state a plausible claim for relief.

Second, to plead an FCA violation, Relator must allege that the fraudulent statement or submission was material to the government's decision to pay the claim. Because her allegations do not satisfy the materiality standard, they must be dismissed under Rule 12(b)(6).

Third, the FCA is a fraud statute, and Relator is required to plead her FCA claims with particularity under Rule 9(b). The vast majority of Relator's allegations fall short of this standard as they do not even identify a specific fraudulent claim submitted to the government, let alone the "who, what where, when and how" of the fraud she alleges. Further, all of Relator's claims under Wis. Stat. § 20.931 must be dismissed, because, despite filing a 227-paragraph

amended complaint, she never identifies a single, specific fraudulent Medicaid claim that was presented to the government for reimbursement.

Finally, Relator's retaliation claim is fatally flawed because it fails to satisfy the elements of 18 U.S.C. § 3730(h). That section requires, among other things, that Relator show: (1) her conduct at Lakeshore was in furtherance of her *qui tam* action; and (2) that Lakeshore knew her conduct was in furtherance of that action when it terminated her employment. Relator has failed to plead facts to sufficient to satisfy these elements of § 3730(h), and her retaliation claim must be dismissed.

Relator, a medical coding specialist by profession, does not appear to understand many of the rules and guidelines that she accuses Lakeshore of violating. Given Relator's glaring pleading deficiencies, the entire Amended Complaint must be dismissed with prejudice.

BACKGROUND

I. FACTUAL BACKGROUND

A. The Medicare Program

Congress created the Medicare program in 1965 as part of the Social Security Act, 42 U.S.C. §§ 1395 et seq., to provide a federally-funded health insurance program for the aged and disabled. CMS administers the Medicare program. Medicare is comprised of four components, designated as Parts A, B, C, and D. Medicare Part A (42 U.S.C. §§ 1395c – 1395i-5) covers services furnished by hospitals and other institution providers. Medicare Part B (42 U.S.C. §§ 1395j – 1395w4) covers "medical and other health services" not covered by Part A. "Medical and other health services" include, but are not limited to, services "furnished in physicians' offices . . . ." 42 U.S.C. § 1395x(s)(1), (2)(A)-(B).

At all times relevant to Relator's allegations, claims for physician services in Wisconsin were reviewed and paid by a Medicare contractor assigned by region and known as the "Carrier."

Physicians, certain non-physician practitioners (NPPs), therapists in private practices (TPPs), and physician-directed clinics that bill for services furnished incident to a physician's service generally submit their claims to their Carrier using the "837 Professional electronic claim format or the CMS-1500 paper form . . . ." CMS Pub. 100-04, Medicare Claims Processing Manual ("MCPM"), § 10—General, http://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Downloads/clm104c05.pdf. Healthcare services provided to patients are represented on these forms by the use of various billing codes, such as CPT (Current Procedural Terminology) or HCPCS (Healthcare Common Procedure Coding System) Level II Code Set. *Id.*; *see also* HCPCS – General Information, http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html.

CMS maintains an Online Manual System, which is used by CMS program components, partners, contractors, and State Survey Agencies to administer CMS programs. See CMS, *Manuals*, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals. These billing guidelines are not statutes passed by Congress after constituents had an opportunity to debate them, and they are not regulations published with notice and an opportunity for comment by the general public or the health care community. Rather, they offer "day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives." *Id.*

B. The Medicaid Program

The Medicaid Program is a health care benefit program established by federal law, 42 U.S.C. § 1396 et seq., to pay for medical services provided to indigent and other qualified individuals. Medicaid is a program jointly funded and managed by the states and the federal government. *Harris v. McRae*, 448 U.S. 297, 301 (1980). CMS administers Medicaid at the federal level, under the aegis of the U.S. Department of Health and Human Services ("DHHS").

Douglas v. Indep. Living Ctr. of S. Cal., Inc., 565 U.S. ---, 132 S. Ct. 1204 (2012). In Wisconsin, the program is run by the Wisconsin Department of Health Services ("WDHS"). *See generally* Wis. Stat. ch. 46. Wisconsin Medicaid claims, which use CPT and HCPCS codes for billing physician services, are reviewed and paid through ForwardHealth, a program of WDHS. *See, e.g.*, https://www.forwardhealth.wi.gov/WIPortal/Default.aspx. WDHS also publishes guidance on various Wisconsin Medicaid billing and reimbursement matters.

C. Relator's Allegations[1]

Relator was employed by Lakeshore for approximately five-and-a-half years until she was terminated on October 11, 2011. (Am. Compl. ¶ 7.) While employed, Relator's job duties included "auditing[,] billing and coding of services administered by [Lakeshore's] healthcare providers." (*Id.*) Relator alleges that, during the course of her employment, she became aware that Lakeshore was engaging in a "systematic and willful practice" of submitting false claims to the United States and the State of Wisconsin. (Am. Compl. ¶ 2.)

All told, Relator alleges ten causes of action, five for violations of the federal FCA (31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), (a)(1)(G), and 3730(h)) and five for violations of Wisconsin's "mini-FCA" (Wis. Stat. § 20.931(2)(a), (2)(b), (2)(c), (2)(h). and (14)). (Am. Compl. ¶¶ 196-227.) Relator's FCA claims are based on twelve separate alleged "schemes" by Lakeshore to defraud the state and federal government. These allegations are discussed in more detail in the Argument Section below.

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[1] When analyzing a motion to dismiss, the Court must accept all allegations in Relator's Complaint as true. *Council 31 of the Am. Fed'n of State, County & Mun. Empl. v. Quinn*, 680 F.3d 875, 884 (7th Cir. 2012).

II. PROCEDURAL HISTORY

Relator commenced this action on September 23, 2011, by filing a Complaint under seal [Docket No. 1], to which Relator appended approximately 238 pages of supporting documents. On May 22, 2012, the United States filed a Notice of Declination to Intervene [Docket No. 11]. Relator then filed a First Amended Complaint ("Amended Complaint") with no supporting attachments [Docket No. 12]. On May 23, 2012, the State of Wisconsin also filed a Notice of Declination to Intervene [Docket No. 13]. The Court issued an Order directing that the Complaint be unsealed and served on Lakeshore, [Docket No. 14]. The parties stipulated to an extension of the deadline for Lakeshore to answer, move, or otherwise respond through August 6, 2012 [Docket No. 17]. Lakeshore now brings this Motion to Dismiss the Amended Complaint.

ARGUMENT

Relator's claims fail to meet the pleading standards of Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. The Amended Complaint should be dismissed in its entirety with prejudice.

I. LEGAL STANDARD

A. The Federal False Claims Act

Relator alleges violations of 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(C) and (a)(1)(G) (2010).[2] Section 3729(a)(1)(A), the "false claim" provision, imposes civil liability on any person who knowingly presents a false claim to the government for payment or approval.

[2] On May 20, 2009, President Obama signed the Fraud Enforcement and Recovery Act ("FERA") into law. Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111–21, 123 Stat. 1617. The FERA amendments included various substantive and procedural changes to the requirements of the FCA. *Cf.* False Claims Act of 1863, ch. 67, 12 Stat. 696 (1863), 31 U.S.C. § 3729-3733 (2008) *and* 31 U.S.C. § 3729-3733 (2010) (as amended by Pub. L. 111-21, 123 Stat. 1621).

To plead a claim under this section, Relator must allege and prove three elements: (1) a false or fraudulent claim; (2) which was presented by Lakeshore to the United States for payment or approval; (3) with the knowledge that the claim was false.

Section 3729(a)(1)(B), the "false statement" provision, imposes civil liability on any person who knowingly makes a false statement to the government in order to get a false claim paid. To plead a claim under this section, Relator must allege and prove three elements: (1) Lakeshore submitted a false record or statement to the United States; (2) that was material to the payment of a false or fraudulent claim; (3) with the knowledge that the statement was false. 31 U.S.C. § 3729(a)(1)(B); *see also United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005) (citing *United States v. Lamers*, 168 F.3d 1013, 1018 (7th Cir. 1999)).[3] A "material" statement under section 3730(a)(1)(B) is one that that has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); *see also Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732-33 (7th Cir. 1999) (affirming dismissal of qui tam FCA claims because relator failed to demonstrate that the omission of a particular test "was material to the United States' buying decision").

To establish a claim under Section 3729(a)(1)(G), the "reverse false claims" provision, Relator must show that Lakeshore "knowingly conceal[ed] or knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the Government . . . ." 31 U.S.C. § 3729(a)(1)(G); *see also* John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.01[L] (Aspen Publishers) (3d ed. & Supp. 2012-1). Anyone who conspires to

[3] Although the Courts in *Gross* and *Lamers* were analyzing the pre-2010 statute, the essential elements of the "false statements" provision are the same.

commit a violation of subsections (A), (B), or (G) is liable under section 3729(a)(1)(C). *See* Boese § 2.01[F].

Under the FCA, a person acts knowingly if he or she "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). Accordingly, the Seventh Circuit has held that "innocent mistakes or negligence are not actionable [under the FCA]." *Hindo v. University of Health Sciences*, 65 F.3d 608, 613 (7th Cir. 1995). The Seventh Circuit has similarly held that minor technical regulatory violations do not make a claim "false" for purposes of the FCA. *Lamers*, 168 F.3d at 1019; *see also Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477-78 (9th Cir. 1996) (holding that imprecise statements or differences in interpretation growing out of a disputed legal question are not false under the FCA).

B. The Wisconsin False Claims Act

In 2007, Wisconsin enacted its own version of the FCA, which is almost identical to the version of the federal statute in use prior to the enactment of amendments under FERA.[4] The Wisconsin FCA imposes liability on anyone who:

> (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
>
> (c) Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance . . . .
>
> (g) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance program.

[4] Wisconsin has not updated its "mini-FCA" to correspond with the amended federal FCA.

Wis. Stat. §§ 20.931(2)(a), (b), (c), (g).

C. Rule 12(b)(6): Failure to State a Claim Upon Which Relief can be Granted.

To survive a Rule 12(b)(6) motion to dismiss, a complaint must provide a short and plain statement of the claim showing that the pleader is entitled to relief such that the defendant is given "fair notice of what the claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Further, the factual allegations in a complaint must be sufficient to raise the possibility of relief above the "speculative level," assuming that all of the allegations in the complaint are true. *E.E.O.C. v. Concentra Health Servs., Inc.*, 496 F.3d 773, 776 (7th Cir. 2007) (quoting *Twombly*, 550 U.S. at 555).

D. Rule 9(b): Failure to State Fraud with Particularity

Rule 9(b) of the Federal Rules of Civil Procedure states: "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." The FCA is "an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b)." *Gross*, 415 F.3d at 604 (citing *United States ex rel. Garst v. Lockhead-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003)). As a result, Relator bears the burden of making detailed allegations, including the "who, what, when, where, and how" of the alleged fraud. *United States ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 740 (7th Cir. 2007); *see also Borsellino v. Goldman Sachs Group, Inc.*, 477 F.3d 502, 507 (7th Cir. 2007).

Under this standard, Relator's Amended Complaint must set forth the time, place, date, methodology, and specific content of each alleged act of fraud. *See Gross*, 415 F.3d at 604. Courts dismiss FCA claims in which the plaintiff merely pleads "by example" or where the

complaint simply alleges a general scheme of fraud. *See, e.g., United States ex rel. Cox v. Iowa Health System*, 29 F. Supp. 2d 1022, 1025 (S.D. Iowa 1998).

II. RELATOR'S FEDERAL FALSE CLAIMS ACT ALLEGATIONS MUST BE DISMISSED, BECAUSE RELATOR FAILS TO STATE A CLAIM AND FAILS TO PLEAD FRAUD WITH PARTICULARITY.

A. The Complaint Does Not State a Regulatory Violation Related to Evaluation and Management ("E/M") Services.

CMS pays physicians and other health care providers for evaluation and management (E/M) services rendered during patient office visits or hospital admissions. Providers may bill CMS for one of five levels of E/M service for new patients (CPT codes 99211 – 99215) and existing patients (CPT codes 99201-99205), or one of three levels of E/M service for initial hospital admissions (CPT codes 99221-99223). American Medical Association, *CPT 2012: Professional Edition,* pp. 9-10 (Declaration of Lousene Hoppe ("Hoppe Decl."), Ex. A.). The E/M code billed (and the amount paid) depends on several qualitative criteria called "components" that are set forth in the CPT coding manual. *Id.* The "components" assessed when billing for E/M services include the complexity of the medical decisions made during the patient visit, the severity of the health-related issues addressed during the visit, and the time the provider spends with the patient, among other factors. *Id.*

Relator alleges two ways in which Lakeshore fraudulently billed for E/M services. First, she alleges that Lakeshore "routinely submitted claim forms for payment of E/M services performed by Lakeshore's healthcare providers at a higher level than was supported by the patient's medical documentation." (Am. Compl. ¶ 63.) Relator states she regularly audited Lakeshore physicians' E/M documentation to verify that it supported the code listed on the physicians' "encounter forms." (Am. Compl. ¶ 43.) She argues that because this documentation often lacked one or more "component" for the E/M code billed, use of that code was fraudulent.

Relator further alleges she attempted to instruct Lakeshore's physicians in proper E/M billing practices by offering more than sixty-three "Provider Education" sessions pursuant to her E/M audits. (Am. Compl. ¶¶ 57, 62.) She asserts that the allegedly improper billing continued despite her "Provider Education" sessions. *See Am. Compl.* ¶ 63.) Notably, Relator does not allege that the physician billed for services that were never provided.

Second, Relator alleges that Lakeshore improperly billed for "screening hemoccult lab tests" performed during office visits for which an E/M service was separately billed.[5] (Am. Compl. ¶ 58.) Relator claims the hemoccult lab test was included in the E/M service billed, and thus the amount paid under the E/M code included payment for the hemoccult lab test. In other words, Relator argues that the hemoccult lab test and E/M service were "bundled" together under one CPT code, and that by billing separately for the hemoccult lab test and the E/M service, Lakeshore improperly "unbundled" those services. Relator alleges this "unbundling" resulted in fraudulent double-billing.

Relator fails to state a claim with respect to her E/M "upcoding" allegations for two reasons. First, CMS pays for E/M services based on the level of service actually provided, not on the medical documentation of that service. Thus, the treating physician, who was present when the services were performed -- not a coder or auditor -- is responsible for designating the appropriate level of service. The fact that the documentation does not contain a notation for every step the physician took when examining and treating the patient is not determinative of the government's payment decision for E/M claims. Second, most of the "upcoded" claims Relator alleges involve differences of only one level. Because E/M coding is inherently subjective, as a matter of law a one-level coding difference cannot be "false" under the FCA. Further, Relator's

[5] A hemoccult test checks for blood in the patient's stool.

allegation of fraudulent hemoccult lab test billing fails to state a claim because CMS's guidance expressly permit the billing practice of which she complains. Finally, she has not pled fraud with particularity with regard to her hemoccult lab test billing allegation.

1. The code for an E/M service is based on the level of service performed, not on the medical documentation.

No federal statute, regulation, or Medicare Manual section, requires or even suggests that providers code E/M services based on the content of a medical record. To the extent CMS addresses the issue at all, it is clear that the level of reimbursement is determined by the services *performed* and not the services *documented.*

For example, the Medicare Claims Processing Manual directs Carriers with regard to E/M coding to: "Instruct physicians to select the code for the service based upon the **content of the service**." MCPM, Ch. 12, § 30.6.1 (emphasis added). Similarly, a 1995 OIG report on E/M coding states: "Accurate coding is achieved when physicians select codes which consistently fit the services physicians actually **provided**." OIG Report No. OEI-04-92-01060, "Physician Use of New Visit Codes," May 1995, http://oig.hhs.gov/oei/reports/oei-04-92-01060.pdf (emphasis added).

Further, the CMS Medicare Contractor Beneficiary and Provider Communications Manual ("MCBPCM"), which describes the use of CPT codes, reinforces the idea that the services performed, not the services documented, determine the appropriate code:

> *CPT Procedure Code Definition* – The CPT procedure code definition, or a descriptor, is based upon the consistent interpretation of the procedure performed in contemporary medical practice and by many physicians in clinical practice. . . . **Only the single CPT code most accurately describing the procedure performed or service rendered should be reported.**

CMS Pub. 100-09, MCBPCM, ch. 5, § 20.12(1)(b) (emphasis added). Once again, the government instructs carriers to use the content of the service, rather than the record, to

determine the proper coding and reimbursement. Thus, an apparent discrepancy between the documentation of an office visit and the E/M code billed for that visit is not enough to render a claim for payment of E/M services false.

Consistent with this general principle, CMS's December 2010 Evaluation and Management Services Guide ("E/M Services Guide") states that "Health care payers *may* require reasonable documentation to ensure that a service is consistent with the patient's insurance coverage . . . ."[6] In other words, such documentation is not required.

The 2010 E/M Services Guide incorporates E/M billing guidelines that were published in 1995 and 1997. In conjunction with the 1995 Guidelines, HCFA[7] and the AMA issued a publication meant to answer anticipated questions about the Guidelines, including the following:

> 1. Are these guidelines required?
>
> No. **Physicians are not required to use these guidelines in documenting their services.** However, it is important to note that all physicians are potentially subject to post payment review. In the event of a review, **Medicare carriers will be using these guidelines in helping them to determine/verify that the reported services were actually rendered**. Physicians may find the format of the new guidelines convenient to follow and consistent with their current medical record keeping. Their usage will help facilitate communication with the carrier about the services provided, if that becomes necessary. Varying formats of documentation (e.g., SOAP notes) will be accepted by the Medicare carrier, as long as the basic information is discernable."

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[6] This resource is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/EMDOC.html.

[7] CMS's predecessor agency.

"Documentation Guidelines for Evaluation and Management Services Questions and Answers", as reprinted in the November 1994 CPT Assistant, at 1 (emphasis added). (Hoppe Decl., Ex. B).[8]

Thus, CMS guidance on this issue is longstanding, overwhelming, and clear. Providers bill Medicare and Medicaid based on the services *provided*, not on the services *documented.* Documentation of services makes review of the provider's billing more efficient. But failure to document a service does not make a claim for that service false under the FCA.

In *United States v. Krizek*, 859 F.Supp. 5 (D.D.C. 1994), *op. supp. by* 909 F. Supp. 32 (D.D.C. 1995), *aff'd in part*, 111 F.3d 934 (D.C. Cir. 1997), the court confirmed that failure to document a service does not render a claim for payment of that service false. In *Krizek*, the government brought an FCA action against the defendant psychiatrist (Dr. Krizek) based on his alleged "up-coding" of E/M services. Dr. Krizek's billing clerk had presumed, in the absence of specific instruction to the contrary, that all of Dr. Krizek's office visits were the longest type of office visit covered, lasting approximately 45-50 minutes. In fact, many of the visits were shorter and deserving of a lower reimbursement. *Id.* at 12. Ultimately, this resulted in Dr. Krizek billing for a suspiciously high number of hours of E/M service, including several days in which he claimed payment for more than 24 hours of E/M services.

Dr. Krizek's records did not indicate how much time he spent with each patient. Nonetheless, the court did not presume that every undocumented E/M claim was false absent evidence to the contrary. The court recognized that Dr. Krizek worked long hours and relied on

[8] If there were ever a question about the veracity of a Lakeshore provider's E/M claim, the Carrier can request the medical records for this claim. If, in the Carrier's opinion, the medical records are insufficient, the Carrier could deny the claim. The Carrier does not have the final say, however. Providers can appeal the denial of claims by Carriers through an administrative process, where the provider could supplement the record or provide testimony by himself or the patient to justify the level of service provided. *See, e.g.*, Office of Medicare Hearings and Appeals, *Understanding the Appeals Process*, http://www.hhs.gov/omha/process/level2/l2_ab.html.

testimony from an expert witness that nine hours of patient service was a very long day. *Id.* The court found that nine hours was a "fair and reasonably accurate assessment of the time Dr. Krizek actually spent providing patient services." *Id.* Claims that exceeded the nine hour benchmark were considered overpayments. Amounts less than that were presumed to be valid. *Id.* With respect to FCA liability, the Court held that only claims exceeding 24-hours in a day would be presumed false. *Id.* Ultimately, only a small percentage of the total claims were determined to be "false." *Id.*

Had the court focused on Dr. Krizek's *documentation*, its inquiry would have been much more straightforward. It would simply have examined Dr. Krizek's files and determined that any claim not supported by sufficient documentation was false unless Dr. Krizek could prove otherwise. But, as noted above, per CMS, it is the services *provided* and not the services *documented* that are material to determining a claim's validity. Therefore, in an FCA action, the burden is on the Relator to show that undocumented services were not performed. Relator has not done so in this case, nor has she pled any such allegations. Accordingly, Relator has failed to state a claim for fraudulent billing of E/M services.

2. One-level coding differences cannot be "false."

As noted above, CMS published E/M Documentation Guidelines in both 1995 and 1997. Both of these sets of Guidelines can be found on CMS's website, on the page that offers guidance for coding E/M services.[9] Even a cursory review of these Guidelines shows that the process for determining the appropriate level of service is complex and inherently subjective.

According to the Documentation Guidelines, three "key components," and up to four other components, define the level of E/M services to be billed. (1995 Documentation

[9] *See* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/EMDOC.html.

Guidelines at 3.) One "key component" is "history," which encompasses inquiries about the patient's chief complaint, the history of the patient's present illness ("HPI"), a review of the patient's current physical condition, and the patient's past, family and/or social history. (1995 Documentation Guidelines at 4.) When billing for E/M services, a provider must assess the time spent exploring this "history," as well as the complexity of that task, in determining how to bill for the service. This assessment is inherently subjective and does not lend itself to a "falsity" analysis under the FCA.

For example, even something as simple as examining a patient's sprained ankle may require several subjective decisions by the provider to determine the appropriate E/M code billed. Suppose the physician recorded the following note in the medical records related to the HPI performed during the visit: "Throbbing pain in ankle for several days. No fx per xray." The appropriate E/M code for the visit may vary depending on whether this HPI is considered "brief" or "extended." A "brief" HPI is one in which the physician has recorded one to three elements of the present illness. An "extended" HPI is one in which the physician has recorded four or more elements. (1995 Documentation Guidelines at 6.) HPI elements include: location, quality, severity, duration, timing, context, modifying factors, and associated signs and symptoms. *Id.*

First, did the physician record an element for identifying the location of the injury? The record does not indicate whether the right or the left ankle was examined. While the x-ray will clearly show which of the patient's ankles was injured, is this also part of the documentation and thus a recorded element? What if the physician neglected to refer explicitly to the examination of the x-ray? Second, consider the term "throbbing." Has the physician recorded the element of "quality," the element of "severity," or both? What if the doctor had recorded the words "sharp" or "strong"? In summary, a reasonable coder could differ as to the appropriate level of HPI to

choose in this situation, which could in turn affect the level of E/M service billed. The uncertainty surrounding these questions is present almost every time a physician bills for an E/M service.

Not surprisingly, the government has acknowledged the inherent subjectivity of E/M coding. Around the time the 1997 Documentation Guidelines were published, the DHHS OIG instituted a nationwide initiative to audit teaching-physician compliance with Medicare billing rules. DHHS conducted these audits in part to address concerns about widespread E/M upcoding. The final audit report concluded:

> One-level differences [in coding E/M services] may indicate legitimate differences in judgment. HCFA, OIG, and carrier staff with whom we spoke acknowledged that coding discrepancies can be subjective and do not necessarily reflect fraud or abuse.

Concerns with Physicians at Teaching Hospitals (PATH) Audits, GAO Report No. GAO/HEHS-98-174, July 1, 1998, page 22, http://www.gao.gov/archive/1998/he98174.pdf (emphasis added).

The majority of the claims cited in paragraphs 32-72 of the Amended Complaint involve one-level E/M coding disputes. But given the subjective nature of E/M coding, such allegations cannot, as a matter of law, form the basis for a false claim under the FCA. *See Hagood,* 81 F.3d at 1477-78 (imprecise statements or differences in interpretation growing out of a disputed legal question are not false under the FCA); *Lamers*, 168 F.3d at 1019 (minor technical regulatory violations do not make a claim "false" for purposes of the FCA).

Moreover, Relator's allegations that Lakeshore has a policy of E/M upcoding are simply not true. In paragraph 55, Relator identifies thirteen Lakeshore physicians and alleges that audits of their E/M claims showed that each of these physicians allegedly used the wrong E/M code somewhere between 12% and 64% of the time. But a review of the Relator's audit results shows that the allegedly high error rates do not result from any systematic attempt by Lakeshore

providers to "upcode" E/M visits. (Hoppe Decl., Ex. C.)[10] In fact, according to Relator's own analysis, two of the providers had no allegedly "overcoded" claims, six providers had only one "overcoded" claim, and three providers had only two "overcoded" claims. Further, of the 325 encounters reviewed, Relator found that thirty-two of the claims were overcoded, whereas fifty-seven of the claims were "undercoded". If Lakeshore physicians had a problem with coding E/M services, it was a problem of undercoding, not a problem of upcoding, as Relator is well aware.

Regardless, where there have been ambiguities in discerning appropriate CPT codes to reflect services rendered, the court has given the benefit of the doubt to the coding physician. *See, e.g.*, *Krizek*, 111 F.3d 934; *United States v. Prabhu*, 442 F.Supp. 2d 1008, 1026 (D. Nev. 2006) (ruling for defendant in FCA case when it found reasonable persons could disagree regarding whether services were billed properly to the government). The Court should do so here as well and dismiss Relator's E/M fraud claims when only one-level coding differences are involved.

3. Relator has not sufficiently pled fraudulent billing with respect to CPT 88270 (hemoccult testing).

Relator has alleged that Lakeshore improperly billed CMS for hemoccult tests performed pursuant to an office visit for which Lakeshore separately billed an E/M service. (Am. Compl. 61(a).) But CMS allows providers to bill once a year for a "hemoccult test" using CPT code 82270 for patients over 50, separately from an office visit. MCPM, ch. 18, §§ 60.1, 60.2. Relator has cited no facts or authority to support her argument that Lakeshore's separate billing of the hemoccult lab tests was a fraudulent "unbundling" of claims. Relator does not appear to understand the coding requirements in the Manual, or has failed to state her fraud claim with

[10] In addressing a motion to dismiss, courts may consider documents that are integral to a plaintiff's claim and incorporated into the complaint by reference. *See, e.g.*, *Venture Associates Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993) (collecting cases).

sufficient particularity to allow Lakeshore to respond. Relator's hemoccult testing claim should be dismissed under Rules 9(b) and 12(b)(6).

B. Relator's Allegations Regarding Diagnostic X-rays of Pre-MRI Orbits Fail to Satisfy the Requirements of Rules 9(b) and 12(b)(6).

Relator alleges that Lakeshore billed Medicare and Medicaid for pre-MRI x-rays without an order for the x-ray by the treating physician. (Am. Compl. ¶ 71-88.[11]) 42 C.F.R. § 410.32(a) provides that diagnostic x-rays provided without a corresponding physician order are not "reasonable and necessary" and thus are not covered by Medicare. Relator argues that Lakeshore's claims for payment of x-rays provided without a physician's order were therefore false. But Relator misstates the law with regard to physician orders and fails to allege a regulatory violation.

A physician's "standing orders" are generic and apply to all patients. In determining regulatory compliance, CMS treats standing orders the same as it treats an order specific to a single patient. *See, e.g.*, Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 12, Section 60 (discussing how "a hospital's standing order policy can be used as a substitute for the individual request by the patient's attending physician" for pathology services); State Operations Manual, CMS Pub. 100-07, Appendix C, Subpart K, D5301 § 493.1241 (requiring the use of standing orders to be "clearly defined in [laboratory] policy, describing which tests may be covered . . . ."). Similarly, the OIG recognizes that "[s]tanding orders are not prohibited in connection with an extended course of treatment []" so long as they do not lead to "abusive

[11] Paragraphs 71-72 are used twice in Relator's Amended Complaint, once at the end of the section alleging upcoding of E/M services and once at the beginning of the section alleging improper billing of diagnostic x-rays of pre-orbit MRIs. The reference here refers to the second set of paragraphs 71-72.

practices." Publication of OIG Compliance Program Guidelines for Clinical Laboratories, 63 Fed. Reg. 45081 (August 24, 1998).

Lakeshore physicians have determined that a pre-MRI orbit x-ray is medically necessary for each patient with a history of welding or grinding of sheet metal and/or metal in his/her eye. To implement this standing order, Lakeshore requires each patient scheduled to receive an MRI to complete a patient safety questionnaire, examples of which Relator attached to her original Complaint (Compl., Ex. DD.) The questionnaire asks whether the patient has (i) done work involving welding or grinding of sheet metal or (ii) had any metal in his/her eye. (*Id.*) The questionnaire implements the standing order for a pre-MRI orbit x-ray for those who answer "yes" to either question.

Each pre-MRI patient questionnaire attached to Relator's original complaint indicates that the patient had either been involved with welding or grinding sheet metal, or had metal in his/her eye in the past. Relator apparently fails to grasp that the questionnaire implements the Lakeshore treating physicians' standing order for pre-MRI orbit x-rays, and that such standing orders meet the physician order requirement of 42 C.F.R. § 410.32(a). She has failed to state a claim.

Moreover, the Amended Complaint fails to plead Medicaid fraud with particularity. Relator fails to identify even one date on which Lakeshore allegedly billed Medicaid for a pre-MRI orbit x-ray. Nor does Relator identify <u>any</u> false record or statement, or provide a specific example of the alleged fraud. Relator's claims alleging fraud against Medicaid must fail under Rule 9(b).

C. Relator's "Vaccines For Children" Allegations Fail Under Rules 12(b)(6) and 9(b).

Relator alleges that Lakeshore falsely billed Medicaid for services that Lakeshore provided in conjunction with the federal Vaccines For Children ("VFC") program.[12] (Am. Compl. ¶ 89.). Specifically, Relator alleges that Lakeshore "maintains a policy and practice to automatically add CPT code 99211 [for outpatient consultations]" to its VFC claims.[13] (Am. Compl. ¶ 90). Providers use CPT code 99211 to bill for a low-level E/M service such as a brief office visit. Relator argues that the addition of CPT code 99211 to Lakeshore's bills is inappropriate because "there is no medical documentation of such consultation and because there was no such consultation." (Am. Compl. ¶ 91.)

Relator fails to state a claim for two reasons. First, WDHS expressly authorizes the billing practice Relator alleges is fraudulent. Second, even if WDHS did not expressly authorize the billing practice at issue, the services provided pursuant to Lakeshore's use of code 99211 are not false because they meet the requirements for reimbursement under that code.

Wisconsin Medicaid reimburses providers for the administration of VFC vaccines to Medicaid-eligible individuals. In February 2007, WDHS issued guidance to assist providers in understanding how to bill for the administration of VFC vaccines. It explained:

> Wisconsin Medicaid reimburses providers for a vaccine's cost and the administration fee using the procedure code of the actual vaccine administered. Providers are required to indicate the procedure code of the actual vaccine administered, not the administration code, on claims. For example, if a provider submits

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[12] The federal government provides free vaccines to providers through the Vaccines for Children program, as a way of incentivizing patients and providers to immunize children who qualify for Medicaid or meet other certain criteria.

[13] Relator incorrectly refers to the visits as "consultation." Consultations are billed using codes 99251-99255. Relator's misuse of this term underscores her recurring lack of understanding of important nuances in coding and billing.

> a claim for a vaccine that is not currently available through the VFC Program, the provider is required to indicate the appropriate procedure code and an amount that includes both the cost of the vaccine and the administration fee. A separate administration fee procedure code should not be indicated.
>
> . . .
>
> If a child is being seen only for immunizations, the provider may also submit a claim for a brief office visit.

"Wisconsin Medicaid and Badgercare Update", http://www.forwardhealth.wi.gov/kw/pdf/2007-24.pdf. Thus, per Wisconsin Medicaid's own billing guidance, providers may bill for a "brief office visit," in addition to billing the appropriate vaccine administration code, whenever a VFC patient visits a provider solely for immunization. In short, Wisconsin Medicaid expressly authorizes the billing practice Relator alleges is fraudulent. Therefore, Relator's VFC allegations fail to state a claim.

Moreover, Relator has not stated a claim because the services for which Lakeshore bills code 99211 meet the requirements for reimbursement under that code. Relator alleges that Lakeshore's claims under code 99211 are false because "there is no medical documentation of . . . consultation" and "there was no . . . consultation." (Am. Compl. ¶ 91). As a threshold matter, this allegation fails to state a claim because the definition of a code 99211 service does not include "consultation." The CPT book defines code 99211 as:

> Office or other outpatient visits for the evaluation and management of an established patient that may not require the presence of a physician. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.

Further, "the reporting of code 99211 is unique among E/M codes in having no key component requirements." American Academy of Pediatrics Committee on Coding and Nomenclature,

When Is It Appropriate To Report 99211 During Immunization Administration?[14] As noted in Section A, *infra*, E/M "key components" include such things as patient history, physical examination, and medical decision making. Documenting the quality and quantity of key components allows Medicare carriers to determine whether the service was properly coded. Here, there is no need to document services provided because doing so is irrelevant to determining whether billing under code 99211 was appropriate. Thus, failure to provide a "consultation" does not render a billing under code 99211 false, nor does failure to maintain documentation of "key components".

Finally, a claim under code 99211 is appropriate even where only minimal services are provided, such as asking the patient a few questions about their general health. (*See id.*) Relator has failed to allege that the services provided pursuant to Lakeshore's billing under code 99211 are so minimal as to make a claim false under that code.

Finally, Relator's VFC claim also fails because she has failed to plead it with particularity. A relator may not "pass go" by merely alleging a general scheme of fraud. He or she must plead with specificity the "circumstances constituting . . . [the] alleged fraudulent conduct." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). Relator has failed to identify any of the particulars of the fraud she alleges. She alleges a general "scheme" of fraud involving a billing policy, but fails to identify any specific instances of fraud. Relator's Amended Complaint lacks any specific allegations concerning individual physicians, supervisors, patients, events, claims, violations, dates, times, actions, or statements. Relator's

[14] This resource is available at http://www.aap.org/en-us/professional-resources/practice-support/Vaccine-Financing-Delivery/Pages/When-Is-It-Appropriate-to-Report-99211-During-Immunization-Administration.aspx?nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token.

generalized allegations, even if presumed true, fall far short of the heightened pleading standard of Rule 9(b).

D. The Complaint Does Not State a Claim for Improper Billing of "Incident to" Services to Medicaid by a Physician Assistant.

Relator claims that Lakeshore falsely billed CMS for services provided by a non-credentialed physician assistant ("PA"). According to Relator, these services should have been provided under Medicare's "incident to" rules, whereby a physician performs the initial visit and establishes a plan of care and then a PA performs follow-up visits under the established plan. Relator claims that Lakeshore did not follow those regulations and allowed a non-credentialed PA to perform initial visits. (Am. Compl. ¶¶ 94-106.)

Relator's allegations fail to state an FCA claim for Medicaid fraud, because Wisconsin Medicaid expressly authorizes the billing practice Relator alleges is fraudulent. Specifically, Wisconsin Medicaid guidance provides that "[c]laims for services provided by a physician assistant must be submitted with the physician assistant's [National Provider Identifier] as the rendering provider and the supervising physician's or the clinic's NPI as the billing provider."[15] Relator alleges Lakeshore submitted bills for physician assistant services in exactly the manner Wisconsin Medicaid instructs. Relator has not pled a violation of Medicaid law and, therefore, her Medicaid claim fails on its face.

E. Relator's Allegations of Fraudulent Billing of Reciprocal Services Fail Under Rules 12(b)(6) and 9(b).

Medicare's reciprocal billing statute and regulations provide that when a physician is unavailable, for whatever reason, to provide services to his or her patients (*i.e.*, the doctor is out

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[15] BadgerCare Plus and Medicaid, Physician Handbook, Certification and Ongoing Responsibilities, Physician Assistants, *available at* https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=50&s=1&c=1&nt=Physician+Assistants.

sick), another physician may deliver those services and bill for them under the absent physician's provider number, assuming certain criteria are met. Relator alleges that Lakeshore falsely billed Medicare for services provided under "reciprocal billing" arrangements that do not meet the necessary criteria. (Am. Compl. ¶¶ 107-17.) Specifically, Relator alleges that Lakeshore submitted claims to Medicare that indicated services had been provided under a reciprocal billing arrangement between physicians when in fact the services had been provided by a "moonlighting" resident, in violation of the relevant regulations. A "moonlighting" resident is one who, while not a fully credentialed physician, is nonetheless allowed to bill Medicare for services provided. Relator contends that Lakeshore engaged in this alleged fraud in order to receive full reimbursement for services provided by "moonlighting" residents when in fact Lakeshore would not be entitled to reimbursement for those services.

Relator's "reciprocal billing" allegations fail to state a claim for two reasons. First, Relator has not identified a violation of any reciprocal billing regulation, requirement, or guidance. Congress has promulgated a statute addressing reciprocal billing arrangements. It includes the following criteria for reciprocal billing:

> (1) the first physician is unavailable to provide the services;
>
> (2) the services are furnished pursuant to an arrangement between two physicians that is informal and reciprocal.

42 U.S.C. § 1395u(b)(6)(D).

In other words, if a physician who is going to miss work because of illness calls a second physician and asks that physician to cover her responsibilities for the day, and the second physician agrees, the covering physician can bill for services under the absent physician's provider number. The statute requires nothing more. Nothing in the statute, implementing regulations, or CMS's guidance requires the arrangement to be in writing or formalized in any

way. Indeed, the fact that a covering physician performs the necessary services for the absent physician is evidence that an informal "arrangement" existed between the two. Moreover, Relator herself refers to this as an "informal" relationship in her Amended Complaint. Relator has not pled or explained how Lakeshore failed to satisfy the reciprocal billing criteria and therefore has not stated a claim.

Second, Relator fails to identify a violation of the statutes and regulations governing "moonlighting" residents. The "moonlighting" statute allows residents to bill for services as if they were fully credentialed physicians. "Moonlighting" regulations promulgated by CMS provide that residents are eligible to bill as fully-credentialed physicians where the following criteria are met:

> (1) the services billed are covered services and would otherwise be payable under Medicare;
>
> (2) the resident is fully licensed to practice medicine in the State in which the service is performed;
>
> (3) the time spent in patient care activities in the non-provider setting is not included in a teaching hospital's full-time equivalency resident count for the purpose of direct GME payments.

See 42 C.F.R. §§ 415.206(b)(1), 415.208(b)(1).

Relator utterly fails to plead or explain why a "moonlighting" resident would be ineligible to bill under a reciprocal billing arrangement. Nor does Relator explain how the moonlighting resident requirements are material to her fraud claim, nor does she allege noncompliance with those requirements.

Finally, Relator fails to plead that Lakeshore did not provide the services for which it billed CMS. In other words, Relator has not alleged that CMS got less than what it paid for. Relator has not pled that CMS would not have paid the amounts claimed if Lakeshore billed for

the services under the "moonlighting resident" rule, and not the "reciprocal billing" rule. Relator simply has not stated a claim for fraudulent billing under the "reciprocal billing arrangement" rule, nor has she pled this allegation with particularity. Her claims under this allegation must be dismissed.

F. Relator Fails to State a Claim for "Upcoding" Screening Pap Smears and Fails to Plead These Allegations With Particularity.

Relator alleges that Lakeshore improperly billed for screening pap smears by "up-coding" them to diagnostic screening pap smears, using CPT Q0091. (Am. Compl. ¶ 126, 127.) Relator's allegations do not state a claim.

Medicare covers a screening pap smear if the patient has not had a screening pap smear within the preceding two (2) years. Medicare covers more frequent screening pap smears for patients who have had a test indicating the presence of cancer, or who are at high risk for developing cancer. 42 U.S.C. § 1395x(nn). A diagnostic pap smear is covered only when ordered by a physician under certain conditions. *See* Medicare National Coverage Determinations ("MNCD") Manual, ch. 1, § 190.2, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html.

CPT code Q0091 is the code billed when providers obtain, prepare, and convey a screening pap smear. *See* MCPM, ch. 18, § 30.5. Thus, Lakeshore bills for screening pap smears under the appropriate CPT code. Relator's pap smear allegations fail to state a claim, because she does not plead or otherwise explain how Lakeshore's pap smear billing policy violated any regulations or resulted in the submission of false claims to the government.

Moreover, Relator's pap smear allegations fail under Rule 9(b), because Relator fails to identify a single date on which Lakeshore allegedly billed Medicare or Medicaid improperly for a "diagnostic screening pap smear." Nor does Relator identify any false record or statement or

provide a specific example of the alleged fraud. Relator has not pled fraud with particularity and her claims must be dismissed.

G. Relators' Allegations of Fraudulent Unbundling of Global Surgical Bills Fail Under Rules 12(b)(6) and 9(b).

Relator claims that under Medicare's "global billing system," providers are required to bill surgeries under certain "global" CPT codes that reimburse providers not only for the surgery itself, but also for certain preoperative, intraoperative, and postoperative services related to the surgery. Relator alleges that in addition to billing the global surgery code, Lakeshore providers bill preoperative visits separately under CPT code 99213, essentially double-billing Medicare for those preoperative visits that are already included in the global code.

Relator's "global billing" allegations fail to state a claim. Relator correctly states that Medicare requires certain preoperative visits to be globally billed if they take place after the decision has been made to operate and are held during the period commencing with the day before the day of the surgery. Relator fails to acknowledge, however, that preoperative visits are properly billed under CPT Code 99213 under a number of circumstances.

Specifically, published CMS guidance provides that billing for a pre-operative visit under CPT Code 99213 is permitted where the visit occurs more than one day prior to major surgery. MCPM, ch. 12, § 40. Relator has not alleged that the visits for which Lakeshore billed CMS using CPT Code 99213 occurred within the "global billing" time period. Further, CMS permits separate billing for diagnostic tests and procedures, visits unrelated to the diagnosis for which the surgical procedure is performed, and for the services of physicians other than the surgeon performing the procedure. (*See id.*) CMS also permits billing separately for E/M services that are provided "on the day before major surgery or on the day of major surgery that result in the initial decision to perform the surgery." (*Id.*) Finally, CMS permits billing separately for E/M

services provided on the day of a procedure when "the patient's condition required a significant, separately identifiable evaluation and management service above and beyond the usual preoperative and postoperative care associated with the procedure or service that was performed." (*Id.*)

Thus, because CMS expressly authorizes providers to bill separately for preoperative E/M services under a wide variety of circumstances, Relator has failed to state a claim by merely alleging that Lakeshore physicians have billed separately for preoperative visits pursuant to surgeries that are also billed under the appropriate global surgical code.

Further, Relator has not pled any specific instances in which Lakeshore providers engaged in billing fraud related to the improper use of the 99213 code or identified any false claims related to this allegedly fraudulent billing. Again, Relator has pled only a "general scheme" of fraud, which is not sufficient to survive a Rule 9(b) motion under the FCA.

H. Relators' Allegations of Fraudulent Unbundling of Follow-Up Ultrasounds from Endovenous Laser Treatments Fail Under Rules 12(b)(6) and 9(b).

Relator contends that limited duplex ultrasounds, which are typically performed after endovenous laser treatments ("EVLT") for varicose veins, are included in the EVLT global procedure code 36478 and should not be billed for separately. (Am. Compl. ¶¶ 141-49.) Relator appears to allege that Lakeshore providers were "unbundling" limited duplex scans from the EVLT codes and charging them separately. However, Relator has failed to state a claim upon which relief can be granted and failed to plead this allegation with particularity.

Wisconsin Physician Services ("WPS"), the Medicare contractor for Lakeshore's region, has issued a Local Coverage Determination (or "LCD") explaining how to bill duplex ultrasound scans performed pursuant to EVLT. *See* "Treatment of Varicose Veins of the Lower Extremities," Local Coverage Determination Number L30142, Wisconsin Physician Services,

available at http://wpsmedicare.com/part_a/policy/active/local/l30143_gsurg041.shtml. The LCD states that while "intra-operative ultrasound services" provided during the EVLT procedure "may not be billed separately," Medicare will pay for "one ultrasound or duplex scan prior to the procedure" and another "within 1 week" of the procedure. *Id.* (emphasis added).

Relator's allegations are confusing and difficult to disentangle. She states that "Lakeshore Providers" perform limited duplex ultrasounds "[f]ollowing an endovenous laser treatment" and improperly bill for such follow-up ultrasounds "in addition to CPT 93971" (the CPT code for the ultrasound that is bundled in the EVLT procedure code). (Am. Compl. ¶¶ 141, 143 (emphasis added)). In addition, Relator confusingly and inconsistently alleges that Lakeshore "instructed providers to bill CPT 76970 instead of 93971", although she never alleges any such bills were submitted. (*Id.* ¶ 144.) Regardless, under the terms of the LCD, the follow-up ultrasound may be separately billed if it is performed within one week of the EVLT procedure. Thus, to the extent Relator alleges that Lakeshore billed for follow-up ultrasounds separate from the original ELVT procedure, that practice is not improper and Relator has failed to state a claim.

Moreover, Relator has failed to allege any facts to support her claim that Lakeshore billed for ultrasound services that were bundled with the EVLT procedures, let alone identify the "who, what, where, when and how" of the fraud alleged. The Amended Complaint does not identify the dates of any false claims by Lakeshore for duplex ultrasounds, nor does it allege that those claims were presented to the government. Likewise, Relator does not identify any false record or statement or provide a specific example of the alleged fraud. Instead, Relator broadly alleges that Lakeshore fraudulently billed Medicare during a period of over six years, based on an irrelevant statement of the number of EVLT procedures performed by one Lakeshore physician

each month. (*Id.* ¶ 147.) Bald allegations do not pass muster under Rule 9(b) and any claim based on such allegations must fail.

I. Relator's Allegation that Lakeshore Medical Violated Medicare Signature Requirements Fails to State a Claim.

Relator claims that one Lakeshore Medical physician, Dr. LaVora, repeatedly insisted on using a stamped signature on his medical documentation in violation of Medicare's signature requirements. (Am. Compl. ¶¶ 150-56). Even a cursory review of the Medicare guidelines reveals that Relator's "stamped signature" allegations fail to state a claim.

Relator correctly identifies CMS's relevant guideline instruction:

> For medical review purposes, Medicare requires that services provided/ordered be authenticated by the author. The method used shall be a handwritten or electronic signature. *Stamped signatures are not acceptable*.

Medicare Program Integrity Manual ("MPIM"), ch. 3, § 3.3.2.4 (emphasis added). However, the remaining allegations are mistaken.

First, Relator refers to the language in the Medicare Manual as a "regulation". This is incorrect. The manuals are CMS's interpretive guidance to providers and contractors; they do not carry the authority of the Medicare regulations.

Second, Relator claims that Dr. LaVora's technical violation of guidelines in CMS's published manuals resulted in Lakeshore submitting false claims for reimbursement. This is also incorrect. The same manual section that disfavors stamped signatures explains that improper or illegible signatures can easily be verified if the author of the medical record entry provides a signature attestation. MPIM § 3.3.2.4[A]. That procedure is outlined in detail in the MPIM. MPIM § 3.3.2.4[C-D]. Therefore, if the Carrier ever chose any of Dr. LaVora's claims for medical review, Dr. LaVora could easily remedy the stamped signature issue and no overpayment would be assessed. Whether or not Dr. LaVora was using a stamped signature,

there is no dispute that the underlying service was provided. Again, the FCA is not a mechanism for enforcement of every technical regulatory or guideline provision.

Thus, Relator fails to state a claim because she has not pled a regulatory violation or identified a single "false claim". Given the Manual's liberal signature attestation system, the use of a stamped signature is easily addressed and immaterial to CMS's reimbursement decision. In addition, Relator has not pled any specific instances in which Dr. LaVoras engaged in billing fraud related to the "stamped signature" issue or identified any specific false claims. Rather, Relator has again pled only a "general scheme" of fraud, which is not sufficient to survive a Rule 9(b) motion under the FCA.

J. Relator's Allegations of Fraudulent Billing of Nursing Home Visits Fail Under Rules 12(b)(6) and 9(b).

Relator alleges that Lakeshore providers "conduct patient visits at nursing home[s] once every thirty days regardless of medical necessity," which results "in claims for an unreasonable number of daily E/M visits by the same physicians to multiple residents at a facility within a twenty-four hour period regardless of medical necessity." (Am. Compl. ¶ 161.) Relator refers to this alleged practice as "gang visits." Relator further alleges that if a patient is not seen for their initial visit or their initial readmission during this one day, Lakeshore providers do not provide an "initial comprehensive visit." (Am. Compl. ¶ 162.) Finally, Relator alleges that the purported "gang visits" result in patients being readmitted by non-physician practitioners who are not eligible for Medicare reimbursement. (Am. Compl. ¶ 164.)

Relator fails to state a claim with regard to her nursing home visit allegations because, even accepting the facts as alleged, she has not stated a violation of the relevant regulations. 42 C.F.R. § 483.40(c) provides that a skilled nursing home facility resident "must be seen by a physician at least once every thirty days." Thus, to the extent Relator alleges that Lakeshore

physicians' monthly nursing home visits are somehow excessive because they occur once every thirty days, she ignores the regulatory mandate of § 483.40(c).

Further, Relator's allegations that Lakeshore providers improperly delegated initial comprehensive visits of readmitted SNF residents fail to state a claim, because the relevant regulations do not require such visits. 42 C.F.R. § 483.20(b)(2)(i) provides that no such comprehensive assessment need be performed during a readmission "in which there is no significant change in the resident's physical or mental condition."

Finally, Relator again makes a series of conclusory allegations without identifying the "who, what, where, when, and how" of the fraud alleged. Relator alleges that "the use of gang visits by [Lakeshore] providers results in patients not receiving initial comprehensive visits from Lakeshore providers." (Am. Compl. ¶ 163.) But Relator pleads not one specific example of this particular alleged scheme. Relator also alleges that Lakeshore providers overbilled CMS pursuant to "gang visits" that resulted in an unreasonable number of E/M claims. Again, however, Relator does not identify a single one of these alleged "gang visits," the physicians who engaged in such visits, or even the number of visits that would be "unreasonable." Relator's utter failure to plead any specific facts makes it almost impossible for Lakeshore to defend against these allegations. Because Relator has not pled the alleged fraud with particularity, this section of the Amended Complaint must be dismissed.

K. Relator's Allegations of Fraudulent Billing of Home Care Services Fail Under Rules 12(b)(6) and 9(b).

Relator alleges that Dr. Wasiullah, a Lakeshore physician, started a program whereby "nurse practitioners would perform a home visit on a patient discharged from the hospital within forty-eight (48) hours of the discharge, even if those patients were also being seen by home health agencies." (Am. Compl. ¶ 175). Relator further alleges that "[Lakeshore] non-physician

practitioners have told Relator that they were being directed by [Lakeshore] providers to bill for home visits for patients who did not qualify [] for home visits as the patients did not have difficulty coming to the provider's offices . . . ." (Am. Compl. ¶ 173.) Thus, Relator appears to claim that Lakeshore fraudulently billed for home care services in two ways: (1) Lakeshore claimed payment for home visits that "overlapped" with services provided by home health agencies; and (2) the medical necessity of performing home visits, rather than office visits, was not properly documented.

Relator cites to the "CMS Internet Only Manual, Chapter 12, § 30.6.14" as support for her first allegation (Am. Compl. ¶ 174.). The CMS Internet Only Manual incorporates and combines all paper CMS manuals for online review. It is not clear which of the paper CMS manuals Relator refers to here. It appears that she is citing to CMS's Claims Processing Manual ("CPM"), however, as Chapter 12, § 30.6.14 of the CPM provides guidance on billing for home care services. Assuming Relator means to cite to the CPM as substantiating her allegation that Lakeshore nurse practitioners cannot bill for home care services where the patient is also being seen by a home health agency, Relator fails to state a claim. Nothing in the CPM prohibits Lakeshore staff from providing home health services and billing for those services.

With respect to Relator's second alleged violation, the CPM states: "For home services provided by a physician using [CPT Codes 99341-99350], the beneficiary does not need to be confined to the home. The medical record must document the medical necessity of the home visit made in lieu of an office or outpatient visit." Thus, per Relator's own cited guidance, the standard for being allowed to bill home visit claims is not whether the patient would "have difficulty coming to the provider's offices," as alleged in the Amended Complaint. In fact, the beneficiary expressly does *not* need to be confined to the home. The physician or nurse

practitioner needs to do is to document the "medical necessity" for the visit "in lieu of an office or outpatient visit."

Finally, Relators allegations fail under Rule 9(b) as she does not identify any particular false claims or statements. Relator fails even to plead that the home visits were not medically necessary. The Amended Complaint merely states that the nurse practitioners who were participating in Dr. Wasiullah's program "did not believe their visit qualified as a billable home visit." (Am. Compl. ¶ 178.) Relator's allegations do not state a plausible FCA claim, fail to plead fraud with particularity, and should be dismissed.

L. Relator's Allegations of Fraudulent Billing for Services Provided by Medical Students Fail Under Rules 12(b)(6) and 9(b).

Relator alleges that Lakeshore improperly billed for physician services in connection with that physician's supervision of "students." (Am. Compl. ¶¶ 182-87). Specifically, Relator alleges that Lakeshore provider Dr. Rosner failed to complete the necessary documentation when billing for such services. (Am. Compl. ¶ 185.) Relator contends that Dr. Rosner's failure to properly document those services resulted in a violation of 42 C.F.R. §§ 415.170 and 415.172, and the submission of false claims to Medicare. An examination of Relator's allegations shows that she is confused about the resident/student billing regulations, and thus fails to state an FCA claim.

First, Relator bases her argument on inapplicable regulations. The Medicare regulations at §§ 415.170 and 415.172 govern payment for services of teaching physicians who are supervising residents. CMS's guidance is clear that residents and students are different:

> Resident – An individual who participates in an approved graduate medical education (GME) program or a physician who is not in an approved GME program but who is authorized to practice only in a hospital setting. . . . .
>
> Student – An individual who participates in an accredited educational program (e.g., a medical school) that is not an approved GME program. **A student is never considered**

> **to be an intern or resident.** Medicare does not pay for any service furnished by a student . . . .

MCPM, ch. 12, § 100 (emphasis added); *see also*, 42 C.F.R. §§ 415.152 (defining "resident" and "teaching physician") and 415.172 (application of subpart to services of teaching physicians supervising residents). Because the regulations cited in the Amended Complaint are inapplicable to medical students, Relator fails to allege a regulatory violation. Moreover, even if those regulations did apply, Relator has failed to include facts sufficient to establish a plausible violation of such regulations.

Additionally, Relator has failed to identify sufficiently the "who, what, where, when and how" of the alleged fraud as required by Rule 9(b). The Amended Complaint does not identify the dates of any false claims by Lakeshore for physicians supervising students, let alone whether those claims were presented to the government. Nor does Relator identify any false record or statement or provide a specific example of the alleged fraud. Rather, Relator's allegations are based on Relator's vague, ambiguous statement that she reviewed "medical documentation" for a one-week period and "found that the documentation did not properly follow Medicare regulations." (Am. Compl. ¶ 186.) Such a statement fails Rule 9(b)'s particularity test and must be dismissed.

M. Relator's Reverse False Claims Allegations Lack Particularity.

The complaint identifies 12 separate categories of allegedly false claims, each of which was discussed *supra*. Five of these types of claims involve the following pattern of allegations: (1) Relator discovers a purportedly erroneous billing practice; (2) Relator notifies supervisors at Lakeshore of the purported errors; and (3) Lakeshore voluntarily changes its billing policy

retroactive to the date Relator discovered the purported errors.[16] The categories of allegedly false claims that fall into this pattern include: (1) billing for medically unnecessary diagnostic x-rays of pre-MRI orbits; (2) submitting claims for reciprocal billing arrangements that do not meet government criteria; (3) billing screening pap smears as diagnostic pap smears; (4) billing limited duplex scans separately from EVLT treatments; and (5) billing for physician services provided when supervising a student without the proper medical documentation.

With limited exceptions, Relator fails to allege that Lakeshore knew about these purported billing errors prior to Relator's discovery. Lakeshore's knowledge of the purported errors is an essential element of Relators' claim under §§ 3729(a)(1)(A), (a)(1)(B). Her failure to plead that element is therefore fatal to her claims under those sections of the FCA. Therefore, Relator's only remaining avenue to bring an FCA action based on the five regulatory violations identified above is the FCA's reverse false claims provision. *See* 31 U.S.C. § 3729(a)(1)(G). However, Relator must still satisfy Rule 12(b)(6) and Rule 9(b) with regard to any allegations brought under § 3729(a)(1)(G). She has not, and her allegations under § 3729(a)(1)(G) must be dismissed.

Prior to the enactment of the FERA Amendments on May 20, 2010, there was significant confusion about whether providers were legally obligated to identify and refund overpayments to CMS absent a government request that they do so. No statute or regulation clearly required such identification and refund, even where the provider became aware of an overpayment. Although the government claimed that the reverse false claims provisions of the FCA required repayment of such funds and penalized the knowing failure to make such repayments, courts generally

[16] As noted in the sections above addressing each individual fraudulent practice alleged by Relator, her identification of supposedly erroneous billing practices is unreliable. Any allegations of changes to Lakeshore's billing practices based on Relator's recommendations should not be viewed as evidence that Lakeshore was billing improperly.

construed the provision to require proof of affirmative acts of concealment of overpayments, not simply knowing retention of funds to which the provider was not entitled. *See, e.g., United States ex rel. Reagan v. East Tex. Med. Ctr. Reg'l Healthcare Sys.*, 274 F. Supp. 2d 824, 855 (S.D. Tex. 2003). Relator has not pled any affirmative acts of concealment with regard to these alleged overpayments and, therefore, to the extent Relator claims recovery of overpayments made prior to May 20, 2010, those claims must be dismissed under Rules 9(b) and 12 (b)(6).

As of May 20, 2010, the FERA amendments expanded the FCA's reverse false claim provision to prohibit "knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreasing[ing] an obligation to pay" the United States. 31 U.S.C. 3729(a)(1)(G). Although neither the statute nor case law have yet defined the term "improperly," at the very least it is limited to expressions of bad faith, not to situations where reasonable coders or providers might disagree about the coverage of a certain item under the Medicare manuals or Medicaid guidance. *See* Boese, § 2.04. As set forth in Sections II.A-K, *supra*, Relator's allegations involve, at best, highly debatable billing issues and cannot form the basis for reverse false claims act liability. *See Lamers*, 168 F.3d at 1019. ("[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations."). Thus, any reverse false claims allegations pertaining to purported overpayments after May 20, 2010, fail to state a claim under Rule 12(b)(6) and must be dismissed.

Moreover, for the reasons set forth in Sections II.A-K, *supra*, Relator has failed to state a claim for a violation of any Medicare or Medicaid regulation or statute, and thus any monies received as a result of the allegedly fraudulent services was not an overpayment. Relator has therefore failed to state a claim for a violation of § 3729(a)(1)(g). Finally, her failure to plead

fraud with particularity with regard to the underlying purported violations is similarly fatal to Relator's § 3729(a)(1)(g) claims.

III. RELATOR'S MEDICAID ALLEGATIONS LACK PARTICULARITY AND MUST BE DISMISSED.

Relator's Second, Third, Sixth, Seventh, Eighth, Ninth, and Tenth Causes of Action include allegations that Lakeshore submitted false claims to the Medicaid program and violated Wisconsin's mini-FCA statute. (Am. Compl. ¶¶ 199-205; 212-27.) Although vague references to the Medicaid program or Medicaid-eligible patients appear in various places in the Amended Complaint, the vast majority of Relator's claims relate solely to alleged violations of Medicare statutes, regulations or guidance. In addition, not one of the specific allegedly false claims that Relator identifies involve a Medicaid patient.

Under both federal and Wisconsin law, a complaint alleging fraud must be pled with particularity. The Amended Complaint identifies no particular Medicaid claims, including dates of service, providers, patients, billing representatives, and so forth. Relator cannot just generally allege a series of fraudulent "schemes" and expect to survive a motion to dismiss. Any causes of action, or portions of causes of action, that related to fraudulent billing of the Medicaid program must be dismissed.

IV. RELATOR FAILS TO STATE A CLAIM FOR RETALIATION UNDER THE FCA.

Relator alleges that Lakeshore retaliated against her for her efforts to address Lakeshore's allegedly fraudulent billing practices. Relator brings her "retaliation" claim under 31 U.S.C. § 3730(h), which provides relief for individuals who are retaliated against because of their conduct "in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section."

Thus, in order to bring a claim under § 3730(h), Relator must show that she has been (1) retaliated against (2) because of lawful acts done in furtherance of her *qui tam* action. *Fanslow v. Chicago Manufacturing Center, Inc.*, 384 F.3d 469, 479-80 (7th Cir. 2004). To satisfy the second element of § 3730(h), Relator must "demonstrate that [her] protected conduct put [Lakeshore] on notice of the distinct possibility of a quit tam action." *Id.* at 483. In evaluating whether a relator has satisfied this element, the Seventh Circuit Court of Appeals applies a "heightened notice standard" for "employees who are charged with discovering fraud in the normal course of their job duties." *Id.*

For example, in *Brandon v. Anesthesia & Pain Mgmt. Assocs.*, 277 F.3d 936, 944-945 (7th Cir. 2002), the court considered whether the relator had satisfied the notice element under § 3730(h). It concluded the relator did not satisfy that element, because he never put defendants on notice that his actions were in furtherance of a *qui tam* action. The court explained:

> It is true that Brandon used terms like "illegal," "improper," and "fraudulent" when he confronted the shareholders about the billing practices. On the other hand, Brandon had never explicitly told the shareholders that he believed they were violating the FCA and had never threatened to bring a qui tam action.
> . . . .
> . . . Brandon's investigation of the billing reports was part of the general course of his responsibilities. . . . the fact that Brandon was alerting his supervisors to the possibility of their non-compliance with the rules would not necessarily put them on notice that he was planning to take a far more aggressive step and bring a *qui tam* action against them or report their conduct to the government.

Id. (citing *Eberhardt v. Integrated Design & Constr., Inc.*, 167 F.3d 861, 868 (4th Cir. 1999) ("(i)f an employee is assigned the task of investigating fraud within the company, courts have held that the employee must make it clear that the employee's actions go beyond the assigned task" in order to allege retaliatory discharge under the FCA); *United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1523 n.7 (10th Cir. 1996) (stating that persons whose

jobs entail the investigation of fraud "must make clear their intentions of bringing or assisting in an FCA action in order to overcome the presumption that they are merely acting in accordance with their employment obligations.").

Relator has not pled facts sufficient to satisfy the heightened notice standard applied to employees whose jobs entail investigating potential fraud. Specifically, she has pled no facts that allege she put Lakeshore on notice that her billing investigations were in furtherance of this *qui tam* action, as opposed to merely satisfying her job duties as a coding analyst. She has not even pled that her conduct at Lakeshore was in furtherance of this action. For this reasons, Relator has not stated a claim under § 3730(h) and the Court should dismiss the retaliation counts of her First Amended Complaint.[17]

[17] Relator has brought claims under the retaliation provision of Wisconsin's "mini-FCA" as well as the federal FCA. There is no case law interpreting the retaliation provision of Wisconsin's "mini-FCA," but given that it mirrors the federal FCA retaliation provision, the Court should apply the same analysis to both.

CONCLUSION

For all the reasons stated herein, Defendant respectfully requests that the Court dismiss Relator's Amended Complaint with prejudice.

Dated: August 6, 2012

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